



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-411/S-014

Eli Lilly & Company
Attention: David O. Clarke, Ph.D., D.A.B.T, R.A.C
Manager, Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Clarke:

Please refer to your supplemental new drug application dated October 26, 2005, received October 26, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Strattera (atomoxetine hydrochloride) Capsules.

This supplemental new drug application provides for the addition of a black box and other labeling changes regarding suicidality and Strattera.

We have completed our review of this application as amended. This application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient package insert submitted October 26, 2005). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-411/S-014.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Richardae Taylor, Pharm.D., Regulatory Project Manager, at (301) 796-1152.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Thomas Laughren
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